DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 09-698/S-031

Wallace Laboratories
Division of Carter-Wallace, Inc.
Attention: llona J. Scott
Half Acre Road/ P.O. Box 1001
Cranbury, NJ 08512-0181

NOV 27 1998

Dear Ms. Scott:

Please refer to your supplemental new drug application (S-031) dated August 4, 1987, received August 7, 1987, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for meprobamate tablets, 200 and 400 mg.

Supplemental application S-031 provides revised final printed labeling. The revisions are described as follows:

1. The phrase “although no causal relationship has been reported” from the statement describing reports agranulocytosis and aplastic anemia in the ADVERSE REACTIONS section of labeling has been deleted. This change is in response to an Agency letter dated January 30,1987.

2. The botanical source of the inactive ingredient ‘starch’ has been added to the Description section.

3. The package insert for "Miltown"-600 mg tablets has been incorporated into the labeling for this NDA.

We have completed our review of supplemental application (S-031) as submitted with final printed labeling on August 4, 1987, and it is permitted.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Should any questions arise concerning this NDA, please contact Ms. Anna Marie Homonnay, Regulatory Management Officer, at (301) 594-5528.

Sincerely yours,

11/23/98

Paul Leber, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research